

REMARKS

Claims 1-37 are pending in the application. Claims 34-37 are new. No claims have been allowed.

At the onset, Applicants respectfully note that the outstanding Office Action and the previous Office Action (dated April 3, 2007) have withdrawn all previous rejections in favor of new grounds for rejection. Applicants respectfully remind the Examiner that “[p]iecemeal examination should be avoided The examiner ordinarily should reject each claim on all valid grounds available” MPEP § 707.07(g). Applicants respectfully urge the Examiner to avoid further piecemeal prosecution and advance this meritorious patent application to issue.

OBJECTIONS TO DRAWINGS

The Examiner objected to the drawings under 37 CFR § 1.83(a) as failing to show the claimed drive mechanism that propels the needle from a resting position to a lancing position. Responsive thereto, the “drive mechanism” has been deleted from claims 1 and 5 by this amendment, which claims were the only claims reciting the drive mechanism. Applicants therefore request that this objection be withdrawn.

CLAIM REJECTIONS 35 U.S.C. § 112

The Examiner rejected claim 18 under 35 U.S.C. § 112 as failing to comply with the enablement requirement. Responsive thereto, Applicants have amended claim 18 to call for actuation of the blocking mechanism breaking the needle body when the lancet system is ejected. Applicants’ amended claim 18 simply recites breaking. It does not require any particular mechanism by which the needle body is broken, nor does it specify how said breaking is associated with the claimed blocking mechanism. For example, one of skill in the art reading Applicants’ specification would be enabled to configure one of the holding elements to break rather than merely moving upon actuation of the blocking mechanism. One of skill in the art would recognize that the claimed breaking of the needle body can be carried out in any number of ways. Applicants respectfully request reconsideration and withdrawal of this rejection.

CLAIM REJECTIONS 35 U.S.C. §103

A. Claims 1-13, 15-18, 20-23, 25, 26 and 29-32

The Examiner rejected claims 1-13, 15-18, 20-23, 25, 26, and 29-32 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,797,942 to Schraga (“Schraga”) in view of

U.S. Publication No. 2003/0114839 to Looper (“Looper”).

Schrage discloses a reusable end-cap for use with a hand held lancing device. With reference to Fig. 2, lancet system 60 includes a needle 61 and a removable cap 62. Lancet system 60 is manually inserted into the lancet receiving assembly 120 and the device is cocked. The cap 62 is removed (and apparently discarded) and the system cap 10 (Fig. 3) is then placed on body 110, at which point the device is ready to be used for a lancing operation. See Schraga, col. 5, lines 25-35. The lancet 60 has cross-shaped ridges 65 whose purpose is not disclosed in the Schraga patent. The system cap 10 is provided with engagement means 30 that allows the used needle to be held and removed by cap 10, so as to avoid exposure of a used needle with the user. The central teachings of Schraga relate to the use of engagement means 30 of end cap 10 to avoid unnecessary exposure to a contaminated needle. Compare Figs. 1 and 3; see, e.g., Schraga, Col. 2, line 54 – Col. 3, line 10.

Looper discloses a surgical instrument assembly 110 (Figs. 2 and 3) that includes a hollow manipulation shaft 120 with a prime mover 130 and an interchangeable surgical tool 160 that connects to the prime mover 130 via a coupler 140, and in particular, to a capture member 150. According to Looper, once the end effector 160 has been utilized and contaminated, a frangible portion 200 such as a notch 210 is distorted or severed to prevent connection. As shown in Fig. 2, the frangible portion 200 is either breakable or distortable to prevent proper coupling to the surgical apparatus. Looper, ¶ [0017].

The Examiner admits that Schraga does not disclose a “blocking mechanism” as claimed by Applicants. Instead, it is the Examiner’s position that it would have been obvious to incorporate into Schraga the method of preventing the distal end effector from connecting with the prime mover, as taught by Looper, to prevent a lancet system from being used more than once. Office Action, pg. 5.

First, setting aside whether it would have been obvious to combine the references as suggested by the Examiner, which Applicants assert is not the case, the combination of Schraga and Looper fails to disclose all of Applicants’ claim recitations. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant’s claims can be distinguished over the cited references); see also MPEP § 2143.03 (“All words in a claim must be considered in judging the patentability of that claim against the prior art.”) (quoting In re Wilson, 4424 F.2d 1382, 1385 (CCPA 1970)).

1. Independent Claims 1, 12 and 21

Amended claims 1 and 12 now call for the protective portion of the needle body and the needle tip being arranged relative to one another in a second position in such a manner

lancing aid and removal therefrom *after use*.” By contrast, Schraga teaches that the cap 62 that the Examiner asserts qualifies as the needle body is removed *before* the lancing aid is used. See Schraga, Col. 5, lines 27-30. Schraga thus teaches away from the claimed invention. McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1354 (Fed. Cir. 2001) (“[A]s a ‘useful general rule,’ . . . references that teach away cannot serve to create a prima facie case of obviousness.”). Applicants therefore respectfully request that the rejection be withdrawn.

2. *Dependent Claims*

All dependent claims depend either directly or indirectly from claims 1, 12 or 21 and are therefore non-obvious over the combination of references for the reasons just noted with regard to claims 1, 12 and 21. However, there are additional reasons supporting the withdrawal of the rejections of the dependent claims.

The Examiner has rejected claims 2, 4-6, 13 and 20 on the basis that “the connection between lancet system 60 [of Schraga] and the lancet receiving assembly is . . . prevented once the lancet system has been removed from the lancing aid.” This assumes, of course, that one of skill in the art would combine the frangible connection feature of Looper with Schraga as asserted by the Examiner. Nonetheless, the Examiner has failed to consider all of the limitations in Applicants’ dependent claims.

For example, claim 2 requires that the lancet system cannot be reinserted into the lancing aid. Even if the connection of the lancing aid and lancet system of Schraga is prevented, as asserted by the Examiner, it is not understood how this equates to preventing reinsertion, as recited in claim 2.

As to claims 7-9 and 22, which recite the various times at which the blocking mechanism is actuated, the Examiner asserts that

it would have been an obvious matter of design choice to modify when the frangible connection is broken because Applicant has not disclosed that actuating the blocking mechanism before, during, or after the lancing operation provides an advantage as used for a particular purpose, or solves a stated problem.

Office Action, pg. 6. First, the Applicants are not required to identify any particular advantage in a U.S. patent application or identify any particular problem being solved. Instead, “in drafting an application, [an applicant] may choose any method he deems desirable . . . so long as he fulfills the description and enablement requirements of 35 U.S.C. § 112.” Weil v. Fritz, 601 F.2d 551, 555 (CCPA 1979). The written description and enablement requirements do not require an applicant to disclose advantages of or problems solved by any particular embodiment or feature. 35 U.S.C. § 112. The statement by the

Examiner is therefore not germane to the rejection. Further, the fallacy of the Examiner's attempt to equate the various times at which Applicants' inventive blocking mechanism can be actuated as being "an obvious matter of design choice" is revealed by comparing the Applicants' claims to the combination of references asserted by the Examiner.

For example, with regard to at least claims 8 and 22, the Examiner's combination of Schraga and Looper would produce an inoperable device. Specifically, claims 8 and 22 recite that the blocking mechanism is actuated upon insertion of the needle body (lancet magazine). Thus, if one were to accept the Examiner's assertion that the blocking mechanism comprises the frangible connection as taught by Looper, and that it would be an "obvious matter of design choice" to actuate such blocking mechanism upon insertion as claimed, the device would not work for its intended purpose. Instead, the connection would be broken and the device would be rendered inoperable before it is ever used. One of skill in the art would not be led by Schraga and Looper to a "design choice" that produces a lancing device which is broken and rendered inoperable before it is used. See McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1354 (Fed. Cir. 2001) ("If references taken in combination would produce a 'seemingly inoperable device,' we have held that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness."); In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984) (error to find obviousness where modifying a reference destroys the function or intended purpose of the device disclosed in the reference).

As to claim 10, the Examiner admits that the cap 62 that she relies on as corresponding to Applicants' claimed protective portion does not meet the limitations of this claim. As the Examiner correctly notes, Schraga explicitly teaches that an entirely different cap (cap 10) conceals and facilitates proper disposal of the contaminated lancet. Indeed, the use of cap 10 to avoid unnecessary exposure to the lancet needle is central to the teachings of Schraga, as explained above. Yet, the Examiner apparently is of the position that it would have been "obvious" to disregard the central teachings of Schraga by avoiding the very cap 10 that Schraga conveniently provides to protect the user from the contaminated needle. Instead, as Applicants understand the Examiner's position, it would have been obvious for the user to remove the cap 10 -- thereby risking an inadvertent puncture from the resulting exposed needle that cap 10 is intended to prevent -- and then insert cap 62 over the needle tip. These extra and wasteful steps defeat the very purpose of the cap 10 and a skilled artisan would therefore avoid them. In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984) (error to find obviousness where modifying a reference destroys the function or intended purpose of the device disclosed in the reference). Applicants respectfully request that the Examiner withdraw this rejection.

The Examiner's rejection with regard to claim 26 is not understood. There is simply no moveable ring disclosed by the Schraga reference that surrounds the needle body.

As to claims 31 and 32, the Examiner states that it is her position that the needle in Schraga is configured to move between the second resting position and the lancing position after the blocking mechanism is actuated. Yet at the same time she asserts the contradictory position that the blocking mechanism breaks the connection between the two elements, rendering further movement between the resting and lancing positions impossible. Thus, implementing the Examiner's combination of references here again produces an inoperable and useless device. See McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1354 (Fed. Cir. 2001) ("If references taken in combination would produce a 'seemingly inoperable device,' we have held that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness."); In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984) (error to find obviousness where modifying a reference destroys the function or intended purpose of the device disclosed in the reference). Applicants respectfully request that the Examiner withdraw this incongruous and inconsistent rejection.

Furthermore, during a telephone interview with the Examiner on June 8, 2007, the Examiner did not initially understand the functionality of the needle moving from a resting position to a lancing position multiple times after the blocking mechanism is actuated. Instead, the Examiner explained to the undersigned that this claimed feature appeared inconsistent with a blocking mechanism that prevents reuse of the needle. These two separate functions were explained by the undersigned during the interview, and Applicants provided a written explanation at the request of the Examiner in Applicants' Amendment of July 31, 2007. The Examiner's failure to initially understand this feature merely illustrates the counterintuitive nature and inventive creativity underlying it. In the same vein, however, Applicants most respectfully request that the Examiner not casually dismiss as "obvious" a counterintuitive claim feature which she failed to appreciate until it was explained to her. Applicants request that this rejection be withdrawn.

B. Claims 12, 14, 21 and 24

The Examiner rejected claims 12, 14, 21 and 24 as being obvious over U.S. Publication No. 20050015020 to LeVaughn ("LeVaughn") in view of Looper. The disclosure of LeVaughn was summarized in Applicants' previous response of July 31, 2007, and is not repeated herein. Looper was discussed above. Of course, the base reference, LeVaughn, has no hint of a blocking mechanism as recited in Applicants' independent claims 12 and 24. Instead, the Examiner summarily asserts that it would have been obvious to provide a

frangible connection like that of Looper between the lancet system (cartridge 50 – Figs. 3 and 4) and lancing aid of LeVaughn.

As was the case with the rejection discussed above, Applicants' independent claims 12 and 21 (from which claims 14 and 24 depend, respectively) can be distinguished over the combination of references. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references); see also MPEP § 2143.03 ("All words in a claim must be considered in judging the patentability of that claim against the prior art.") (quoting In re Wilson, 4424 F.2d 1382, 1385 (CCPA 1970)).

Claim 12 calls for the protective portion of the needle body being positioned in the first position when the lancet system is removed from the lancing aid and further recites that the protective portion at least partially surrounds the needle body in the first position. The Examiner has apparently overlooked the fact that LeVaughn discloses no such feature. Instead, when the lancet is removed from the lancing aid of LeVaughn, the needle tip is exposed from the cover 147 that the Examiner asserts corresponds to the claimed protective portion.

Second, the Examiner apparently is asserting that the spring element 74 (Fig. 4) of LeVaughn corresponds to the claimed holding element of the needle body. However, the spring element 74 is in fact a component of the magazine cartridge, not the needle body. That is, the spring 74 is used to retract the lancet, and not to interact with a holding element of the lancing aid when the lancet system is inserted into the lancing aid, as recited in claim 12. Thus, in accordance with the Examiner's own characterization of LeVaughn, LeVaughn does not disclose a holding element of the needle body as claimed.

Third, even if the Examiner's suggestion to provide a frangible connection like that of Looper between the lancet system (cartridge 50 – Figs. 3 and 4) and lancing aid of LeVaughn were implemented, it would still fail to meet Applicants' claim 12. Claim 12 calls for "a blocking mechanism *in the needle body*." The Examiner has asserted that needle bodies 144 of LeVaughn correspond to the claimed needle body. However, the Examiner also asserts that the blocking mechanism is between the lancing aid and the lancet system, not the needle body. Thus, providing the needle bodies of LeVaughn with a "blocking mechanism" as recited by Applicants would not prevent the cartridge 50 from being reinserted into the lancing aid.

Because Applicants' claim 12 can be distinguished over LeVaughn for at least the three reasons just discussed, Applicants request that the rejection be withdrawn.

The combination of LeVaughn and Looper is similarly deficient as regards

that the needle tip extends from the protective portion of the needle body. The Examiner has asserted that the claimed protective portion reads on cap 62. Office Action, ¶ 6. But Schraga teaches that cap 62 is removed and discarded before the lancet 60 is enclosed by the re-usable cap 10. There is no hint in Schraga of the needle tip extending from the cap 62 at any time. Indeed, allowing the needle tip to extend from cap 62 would defeat the very purpose of the cap 62, which is to enclose the needle tip until the user manually removes it. Thus, Schraga's disclosure regarding cap 62 actually teaches away from Applicants' claimed needle tip that extends from the protective portion in a second position. See Ormco Corp. v. Align Technology, Inc., 463 F.3d 1299, 1308 (Fed. Cir. 2006) (reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the applicant). Schraga fails to disclose a protective portion of the needle body as claimed by Applicants, and Applicants therefore respectfully request that the rejection be withdrawn. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references); see also MPEP § 2143.03 ("All words in a claim must be considered in judging the patentability of that claim against the prior art.") (quoting In re Wilson, 4424 F.2d 1382, 1385 (CCPA 1970)).

Further, claim 12 calls for the protective portion of the needle body being positioned in the first position when the lancet system is removed from the lancing aid. Claim 12 also recites that the protective portion at least partially surrounds the needle body in the first position. The Examiner has apparently overlooked the fact that Schraga does not disclose such a feature. Instead, when the lancet is removed from the lancing aid of Schraga, the needle is exposed. The protective cap 62 (which the Examiner asserts corresponds to the claimed protective portion) has already been removed before cover 140 is installed and thus before a lancing operation ever takes place. Since Schraga does not disclose a protective portion of the needle body that at least partially surrounds the needle body when the lancet system is removed from the lancing aid, Applicants respectfully request that the rejection be withdrawn. Id.¹

Claim 21 calls for the needle occupying the second resting position when the needle body is removed from the lancing aid, and further recites that the needle body at least partially surrounds the tip in the second resting position. Schraga does not disclose this feature. As discussed above, when the lancet is removed from the lancing aid of Schraga, the needle is exposed because the protective cap 62 has already been removed and discarded. Furthermore, Applicants' claim 21 calls for "a needle body configured for insertion into a

¹ To the extent the Examiner is of the position that the cap 62 of Schraga could be replaced after the device is used, as discussed below with regard to claim 10, pg. 13, Schraga teaches away from such a wasted step.

independent claim 21. Claim 21 calls for the needle occupying the second resting position when the needle body is removed from the lancing aid, and further recites that the needle body at least partially surrounds the tip in the second resting position. Again, however, neither LeVaughn nor Looper disclose such a feature. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references); see also MPEP § 2143.03 ("All words in a claim must be considered in judging the patentability of that claim against the prior art.") (quoting In re Wilson, 4424 F.2d 1382, 1385 (CCPA 1970)).

Second, claim 21 calls for the blocking mechanism changing the shape of the needle body and preventing use of the needle body with the lancing aid after the needle body is removed from the lancing aid. Again, since the Examiner is relying on element 144 of LeVaughn for the needle bodies, this recitation is not met. Instead, the Examiner suggests to provide a frangible connection between the cartridge 50 and the lancing aid, which would not change the shape of the structure 144 of LeVaughn that the Examiner has asserted corresponds to the claimed needle body.

Applicants respectfully request that the Examiner withdraw the rejection of claims 12 and 21. Further, since claims 14 and 24 depend from claims 12 and 21, respectively, they too are non-obvious over the combination of references, and Applicants request that the rejection be withdrawn.

ALLOWABLE SUBJECT MATTER

Applicants acknowledge with appreciation the Examiner's recognition that claims 19, 27-28 and 33 would be allowable if re-written in independent form. Responsive thereto, Applicants have added new claims 34-37, which correspond to claims 19, 27-28 and 33, respectively, rewritten in independent form.

CONCLUSION

Applicants believe that the foregoing is a complete response to the outstanding Office Action and reconsideration is requested. Specifically, Applicants believe that all claims are now in condition for allowance and allowance thereof is earnestly solicited.

In the event Applicants have overlooked the need for a Petition for Extension of Time or payment of fee (except for Issue Fees), Applicants hereby petition therefor and authorize the United States Patent and Trademark Office to charge any additional fees for extension of time to Deposit Account No. 02-3223, Bose McKinney & Evans LLP.

If the Examiner has any questions regarding any of the foregoing, she is invited to telephone the undersigned at the telephone number listed below.

Respectfully submitted,

BOSE MCKINNEY & EVANS LLP

A handwritten signature in black ink, appearing to read 'Michael C. Barrol', is written over a horizontal line.

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